Final public minutes of the Working Group meeting I in 2024

Analytical methods and Physico-Chemical properties and Physical hazards (APCP)

(Meeting date: 14 March to 19 March 2024 – virtual meeting)

02 April 2024

1. Welcome and apologies

The meeting was a virtual meeting. The Chair welcomed the participants of the working group meeting. 52 members and nine stakeholders were registered for the meeting. The list of registered participants and observers can be found in annex I to the minutes.

2. Administrative issues

The chair reminded about the security rule for connecting to the meeting and informed about the physical security information distributed to all locally present participants.

The chair shared some reflections on the purpose and goal of the working group meetings.

3. Agreement of the agenda

The Chair introduced the draft agenda and invited the working group members to include any additional items under any other business (AoB).

There was one proposal for an additional agenda point under "Other Information" proposed and accepted by the WG.

"Discussion about the relevance of the experience regarding physical hazards for particular case of active substance renewals (BE)"

4. Declarations of potential conflicts of interest in relation to the agenda

The Chair invited all working group members to declare any potential conflicts of interest in relation to the agenda. None was declared by the working group members.

5. Agreement of the draft minutes from WG I 2023

Two comments on the minutes of WG IV 2023 were received in the commenting period. The working group members reviewed and accepted the proposed changes of the draft minutes. The draft minutes were modified accordingly and were agreed by the working group members.

6. Active Substances

6.1. Medetomidine PT 21

The open issues were discussed and agreed by the working group members.

6.2. Dinotefuran PT 18

The open issues were discussed and agreed by the working group members.

6.3. 5-Chloro-2-methyl-2H-isothiazol-3-one (CIT) PT 6

The open issues were discussed and agreed by the working group members.

6.4. Polymeric betaine PT 8

The open issues were discussed by the working group members. Additional information on one endpoint was requested and agreed upon in written consultation after the meeting. Additional information was requested by the WG regarding the reference specification, which was discussed and agreed in an ad-hoc meeting on 19 March 2024.

7. Union Authorisations

7.1. UA for a product family containing Hydrogen peroxide PT4

The open issues were discussed and agreed by the working group members.

7.2. UA for a product containing Propan-2-ol PT2

The open issues were discussed and agreed by the working group members.

7.3. UA for a product family containing Propan-1-ol;Propan-2-ol PT1

The open issues were discussed and agreed by the working group members.

7.4. UA for a product family containing Mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT) PT 4, 11 and 12

The open issues were discussed and agreed by the working group members.

7.5. UA for a product family containing Margosa extract from cold-pressed oil of the kernels of Azadirachta Indica extracted with super-critical carbon dioxide PT 19

The open issues were discussed and agreed by the working group members. For one aspect of the storage stability test, more information was requested by the WG, which was reviewed and discussed and agreed upon in an ad-hoc meeting on 15 April 2024.

7.6. UA for a product family containing Peracetic acid PT2, 3 and 4

The open issues were discussed and agreed by the working group members.

7.7. UA for a product containing Glutaral (Glutaraldehyde);Mixture of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) PT6, 11 and 12

The open issues were discussed and agreed by the working group members.

8. Technical and guidance related issues

8.1. TAB proposal - classification of peracetic acid solutions as organic peroxides

While the WG agreed on the intention of the proposal, there were concerns regarding the clarity, specifically the text might be read as excluding the possibility to make use of the specific UN RTDG 3149.

It was clarified that the intention is to clarify the status of water in mixtures of peracetic acid, acetic acid, hydrogen peroxide and water for the sole purpose of deciding on the classification type as organic peroxide in case the decision in box 16 of figure 2.15.1 of the CLP regulation is relevant for that decision. It is still the opinion of the WG that in this case type F is the appropriate classification.

It was mentioned that while classification may be decided on when relying on UN RTDG entry 3149, this does not automatically imply waiving of all test requirements.

The concerns will be taken into account for drafting a new version of the TAB proposal

8.2. 8.2 TAB proposal - rewording of "7.3. Using DSC for waiving [...]"

The working group reviewed the proposed changes to the TAB entry 7.3 which are intended to clarify the reporting of decomposition energies. The removal of "ΔH" to avoid ambiguity was agreed unanimously. The working group discussed whether the explicit prescription of using a negative sign for the decomposition energy and not using the negative sign when the value is stated as "exothermic" is useful or whether this statement is self-evident. Finally the working group agreed that retaining this statement add to the clarity.

The agreed new text is:

> *"Reporting:*
>
> - *Exothermic decomposition energy: negative value; unit: J g-1*
> - *If stated as "exothermic", the negative sign should be omitted*
> - *All exothermic decompositions with onset temperatures up to 500 °C must be considered and summed up.*
> - *Report the equipment type, heating rate and exact crucible type.*
> - *Precisely define the metrics used (e.g. onset temperature determined via extrapolation) to avoid confusion."*

8.3. TAB proposal - specification for dossier with multiple sources

The working group discussed the wording of a new TAB proposal describing the procedure by which specifications are to be derived for applications with multiple reference sources. The subject had been discussed already in WG IV 2023 and the text proposal had been commented in an e-consultation from 14 December 2023 to 1 March 2024.

The working group agreed on using the term "specification" in line with the definition also for specifications derived from multiple sources. The discussion highlighted the distinction between "reference specification" and "specification" and agreed on an amendment to clarify this aspect.

The proposed text was agreed upon with small amendments. The final text is the following:

> *"In case of several sources for one active substance dossier (e.g. a task force), one specification which captures all sources should be set. This is done by considering*

the specification for each source independently and combining the "worst case" concentrations of the active substance and the impurities to achieve the specification, i.e. lowest content of active substance and highest content of impurities. Note that all impurities should be stated in the specification, even if only present in one source. This specification is the basis to set the reference specification."

9. Other Information

9.1. Discussion about the relevance of the experience regarding physical hazards for particular case of active substance renewals (BE)

The working group discussed a question put forward by BE regarding the possibility to waive physical hazard testing based on experience in handling for an active substance renewal assessment.

While the WG considered that waiving can and should be applied wherever the guidance forsees this and the justification is scientifically sound, there was no support for specific additional waiving possibilities at the renewal stage. It was highlighted that many requirements under BPR/CLP were not required under BPD/DSD and need to be addressed in renewal. It was also pointed out that test conditions in physical hazard tests will not be encountered in daily handling and therefore the lack of observations of physical hazards in experience is not a convincing argument.

9.2. Other information

- 10 years of working group meetings
- Status update on the in-situ discussions
    - Proposed update of CA document CA-July19-Doc.4.1 to clarify technical equivalence requirements and possible variations in composition between approved active substance and biocidal product
    - Tentative plan:
        - April 2024 – restart of *in-situ* TF work (as needed) on potential revision of previously drafted recommendation parts May/June 2024 – WG commenting on compiled draft recommendation
        - WG-II-2024 – potential discussion on outstanding issues
        - Q3 2024 – addressing the comments
        - WG-III-2024 – expected approval of revised *in-situ* recommendations by BPC WGs
        - November BPC meeting – BPC endorsement of final updated recommendation
- AS working procedure revised
    - No embedded documents, please
    - Reference to one substance - one assessment
    - Combined consultation on Art 5(2) and candidates for substitution
    - Lessons learnt from AS accordance check
        - BPR Guidance applicability: guidance published 6 months before submission
        - of a dossier - for applicants
        - of an Assessment Report - for eCAs
        - The eCA needs to conclude on critical endpoints – exclusion criteria (CMR, ED, PBT, vPvB) even in case of an unacceptable risk and/or if it would not change the final conclusion

        - Questions arising on the clarity and applicability of the measures proposed by the COM on the extension of the Review Programme beyond 2024
        - *CA-Dec23-Doc.5.4 - Extension of RP beyond 2024*
        - In case of doubts or deviations from procedure in your evaluation
        - Contact ECHA
        - Early consultation with WG, ED EG, PBT EG
    - AS final Assessment reports
        - The public Assessment reports must not contain embedded documents
        - If relevant, the eCAs need to include the information from the embedded files into the AR
        - Background: embedded documents cannot be opened from a pdf file, resulting in access to data requests for such documents
    - Third AS info session for CAs
        - 26 March 2024 (14-17 Helsinki time)
    - Ad-hoc follow-up agenda item 6.4
        - New data/waiver submitted by APP by 2 April to EL
        - EL to provide an assessment to ECHA by 4 April
        - WG consultation 5 April to 12 April
        - Ad-hoc WG meeting if required 15 April
        - DL submission of updated CAR to BPC 18 April
    - Ad-hoc follow-up agenda item 7.5
        - New data to be submitted by APP by 4 April to FR
        - FR to provide an assessment to ECHA by 5 April
        - WG consultation from 5 April to 12 April
        - Ad-hoc WG meeting if required 15 April
        - DL submission of updated CAR to BPC 18 April

    - Next WG meetings (see timelines distributes in WG IV 2023)
    - Additional information to "classification of organic peroxides" training
    - summary of e-consultations
        - APCP e-cons - handling of carriers (BE)
            - Will be proposed for discussion for a subsequent WG meeting
        - APCP e-cons - waiving arguments self-reactivity and explosivity (DE)
            - eCA is content with the results and will continue evaluation

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Annex 1 - List of attendees registered for the meeting

Country	Member state participant	
AT	Erich	NEUWIRTH
AT	Isabel	KRIEGL
AT	Michael	GHOBRIAL
AT	Natalie	HOFMANN
BE	Anastasia	BURMISTROVA
BE	Céline	LEROY
BE	Kim	SWENNEN
BE	Minh-Dung	DANG THY
BE	René	BAY
BE	Samuel	HUERGA-FERNÁNDEZ
BE	Steven	FAUCONNIER
BE	Yannick	HERREMANS
CH	Michael	AESCHBACHER
CZ	Martin	VLASAK
DE	Daniela	WINTRICH
DE	Tobias	DEDEN
DE	Ulrike	MÜHLE
DK	Katrine	DOMINO
EE	Imre	VALLIKIVI
EL	Evangelia	TZANETOU
EL	Ioulia	MOSCHOU
EL	Panagiotis	GATOS
ES	Beatriz	MATARRANZ GARCIA-PATOS
ES	David	CANO
ES	VIRGINIA	VALVERDE TORONJO
FI	Katariina	VUORENSOLA
FR	Annabelle	GOUR
FR	François	LUTZ
FR	Léna	NDIAYE
FR	Thérsè	SIX
IT	Lucilla	CATALDI
NL	Alena	BOURKE
NL	Peter	VAN RIJNSBERGEN
NL	Sabine	KRUIDHOF

NO	Ingrid	GJERDE
NO	Marianne Stave	SEKKENES
PL	Anna	HORCZYCZAK
PL	Justyna	JONIK
PL	Magdalena	JURASZEK
SE	Anh	JOHANSSON
SE	Göran	MARSH
SE	Katrin	BÄCKSTRÖM
SE	Nicklas	SELANDER
SI	Klavdija	ZIRNGAST
SI	Špela	VELIKONJA BOLTA
SK	Marian	MASAR
SK	Zuzana	DRABOVA KUSIKOVA

Accredited Stakeholder Organisations (ASOs)		
CEFIC	Boris	VAN BERLO
CEFIC	Laura	PEDRAZA
A.I.S.E.	Marie	REGNIER
CEFIC	Maria Jose	RODRIGUEZ DOPAZO

Applicants
LKC Chem-Regs Ltd
Rütgers Organics GmbH
ECOLAB
CSI
Agrobiothers Laboratoire

ECHA staff
Uphoff Andreas
Marcon Eva
Honka Anni
Hamalainen Eva
PAPADAKI Paschalina
Volpatti Francesco

Human Health WG-I-2024

Final minutes

11 June 2024

Minutes of Human Health WG-I-2024

12-13, 19-22 March 2024

Meeting of the Human Health Working Group of the Biocidal Products Committee

10.1. Welcome and apologies

The Chair welcomed the participants indicating that there are 151 registered participants, of which 97 were members or advisers. One Commission representative was registered for item 8.2, and two EFSA representatives for item 6.2. Three stakeholder representatives and four experts were registered. Applicants were registered for their case-specific discussions.

The list of attendees is given in Annex 1.

The Chair gave a brief presentation on the mandate and tasks for the WG, and the roles of the members, secretariat, applicants and Associated Stakeholder Organisations.

10.2. Administrative issues

SECR reminded that recording of the meeting is not allowed. All meeting participants need to be registered and late registration is not possible.

10.3. Agreement of the agenda

The Chair introduced the draft agenda and invited any additional items. The agenda was agreed without changes.

10.4. Declarations of potential conflicts of interest in relation to the agenda

The Chair invited all members to declare any potential conflicts of interest in relation to the agreed agenda. None were declared.

10.5. Agreement of draft minutes from WG-IV-2023

The minutes were agreed without further changes.

10.6. Active substances

6.1 Medetomidine, PT 21 (eCA NO)

The WG concluded that medetomidine has endocrine disrupting properties with respect to humans.

6.2 Dinotefuran, PT 18 (eCA BE)

The WG maintained the NOAEL values as set at the initial approval, agreeing on the following reference values:

- $AEL_{medium\text{-}term}$ = $AEL_{long\ term}$= ADI = 0.22 mg/kg bw/d
- AEL_{acute} = ARfD = 1.25 mg/kg bw

6.3 5-Chloro-2-methyl-2H-isothiazol-3-one (CIT), PT 6 (eCA FR)

There were no open points.

6.4 Polymeric betaine, PT 8 (eCA EL)

The exclusion criteria were considered not to be met.

The WG agreed on the following reference values:

- AEL_{acute}, $AEL_{medium\text{-}term}$, $AEL_{long\text{-}term}$: 0.03 mg/kg bw/d

- ADI, ARfD: 0.18 mg/kg bw/d

6.5 In situ generated active chlorine - ED assessment (eCA NL)

The WG agreed that further in vivo studies can be waived, considering it unlikely that potential endocrine effects would occur under real-life conditions in humans.

10.7. Union authorisation applications

7.1 UA for a product family containing Hydrogen peroxide, PT 4 (eCA AT)

Please refer to the confidential minutes provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3.

7.2 UA for a product containing Propan-2-ol, PT 2 (eCA FI)

Please refer to the confidential minutes provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3.

7.3 UA for a product family containing Propan-1-ol; Propan-2-ol PT 1 (eCA DE)

Please refer to the confidential minutes provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3.

7.4 UA for a product family containing Mixture of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT), PT 4, 11 and 12 (eCA NL)

Please refer to the confidential minutes provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3.

7.5 UA for a product family containing Margosa extract from cold-pressed oil of the kernels of Azadirachta Indica extracted with super-critical carbon dioxide PT 19 (eCA FR)

Please refer to the confidential minutes provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3.

7.6 UA for a product family containing Peracetic acid PT 2, 3 and 4 (eCA NL)

Please refer to the confidential minutes provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3.

7.7 UA for a product containing Glutaral (Glutaraldehyde);Mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) PT 6, 11 and 12 (eCA FR)

Please refer to the confidential minutes provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3.

10.8. Article 75(1)(g) requests

8.1 Zineb (eCA IE)

The ED assessment of Zineb through read-across from Mancozeb was considered appropriate. There is sufficient evidence to conclude that Zineb is an endocrine disrupter with regard to human health.

8.2 Coarse spraying with corrosive products (SECR)

Please refer to the confidential minutes provided to Member State Competent Authorities in Interact.

10.9. Technical and guidance related items

9.1 Dietary risk assessment for skin repellents

Please refer to the confidential minutes provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3.

9.2 Revision of ECHA Guidance Vol III Parts B+C

Please refer to the separate publicly available minutes.

10.10. Any other business

10.1 Survey on use of disinfectants and causes for incidents

BE provided a presentation on a survey on use of disinfectants and causes for incidents in Belgium. The presentation is available in Interact for MSCAs and ASOs.

The incidences were not related to any specific active substance.

SECR noted the need to consider the lack of understanding instructions when discussing risk management measures.

10.2 Other information

SECR provided a presentation that is available in Interact for MSCAs and ASOs.

Concluding on exclusion criteria

SECR presented the change as established in CA-Dec23-Doc.5.4. This means in principle that in the absence of CLH, the WG has to conclude whether exclusion criteria are met, including whether they meet the criteria to be classified as CMR Cat 1A/1B. Harmonised classification and labelling is under the remit of RAC.

Critical WG conclusions will be needed when CMR properties are seen and it is necessary to decide between Cat. 1 (exclusion) and Cat. 2 (not exclusion). Following a WG discussion on meeting exclusion criteria, RAC may come to a different conclusion.

The members reflected on this, making the following notes:

- Differentiation between Muta Cat. 1B and Cat. 2 could be especially challenging.
- It could be considered that the view from each MSCA could be required, in principle introducing voting.
- A targeted focus group could be established to conclude and vote on meeting exclusion criteria.
- Concern was expressed that much more discussion time (meeting time) could be needed in comparing with the CLP criteria and guidance.
- Before final conclusions, it could be helpful if RAC could somehow be involved.

Next WG meetings

The provisional timing of the next WG meetings is as follows:

- 10-20 June 2024 (virtual)

For this meeting, items should be requested to be included on the agenda by 29 April (including early WG discussions).

An e-consultation should be launched by 10 April if intended to be discussed in this meeting.

- 23 September – 4 October 2024 (provisionally physical/hybrid)

  For this meeting, items should be requested to be included on the agenda by 12 August (including early WG discussions).

  An e-consultation should be launched by 23 July if intended to be discussed in this meeting.

Annex 1

Human Health WG attendees

WORKING GROUP MEMBERS

COUNTRY	NAME	SURNAME
AT	Angelika	DERLER
AT	Christine	HÖLZL
AT	Ingrid	HAUZENBERGER
AT	Isabel	KRIEGL
AT	Max	KINZL
AT	Patrick	HOCHEGGER
BE	Anis	HOUAMED
BE	Céline	LEROY
BE	Charline	AZZOPARDI
BE	Noëmie	EL AGREBI
BE	Yannick	HERREMANS
CH	Daniela	GOLDINGER
CH	David	GRÜNIG
CH	Frédéric	SANS-PICHÉ
CH	Manuel	RUSCONI
CH	Nadine	ROSSIER
CZ	Jan	MIKOLAS
CZ	Petr	SEDLAK
DE	Andrea	HOLZWARTH
DE	Anna	SONNENBURG
DE	Annetta	SEMISCH
DE	Benedikt	PIORR
DE	Dagmar	HOLTHENRICH
DE	Dimitra	ELEFTHERIADOU
DE	Florian	PADBERG
DE	Heiko	SCHNEIDER

DE	Isabel	GÜNTHER
DE	Kathrin	BISSANTZ
DE	Kathrin	GOTTLOB
DE	Kristin	HERRMANN
DE	Michael	ROITZSCH
DE	Saskia	KLUTZNY
DE	Soyub	RIME
DE	Susann	MATTHES
DE	Susanne	RUDZOK
DK	Max	HANSEN
DK	Stine	JENSEN
EE	Triinu	VIHMANN
EL	Anastasia	REPOUSKOU
EL	Dimitra	NIKOLOPOULOU
EL	Niki	ARAPAKI
ES	Eduardo	DE LA USADA MOLINERO
ES	José María	SÁNCHEZ
ES	María Teresa (Matie)	HERNÁNDEZ MOLINERO
ES	SOFÍA	ÁLVAREZ
FI	Anna-Maija	HÄMÄLÄINEN
FI	Elina	RYDMAN
FI	Elina	VÄLIMÄKI
FI	Tuija	HYVÄRINEN
FR	Annabelle	GOUR
FR	Arnaud	GALLIÈRE
FR	Aurélie	AUBIN
FR	Caroline	BOITIER
FR	Elisabeth	MAXIMILIEN
FR	Elodie	COLLIN
FR	Hugo	SAVARD

FR	julia	LORI
FR	Julia	VARET
FR	Lancelot	SEYDOUX
FR	Léna	NDIAYE
FR	Mathieu	KERGUELEN
FR	Perrine	CAPDEVILLE
FR	Roua	BOU ORM
FR	Tiffany	AMSALLEM
FR	VALERIE	BELLINGARD
IE	Alan	BREEN
IT	Edlira	DEKOVI
LU	Christina	ROHLES
NL	Angelique	WELTEN
NL	Carina	BOS
NL	Marijke	SCHUTTE
NL	Suzanne	VAN DEN BERG
NO	Astrid	GAUSTAD
NO	Birgitte	LINDEMAN
NO	Hilde	ANDERSEN
NO	Hilde Karin	MIDTHAUG
NO	Marit	RANDALL
NO	Sara	KJÆRVIK
NO	Tonje Danielsen	RONGVED
PL	Justyna	DUDEK-NOWAK
PL	Monika	UJMA-CZWAKIEL
PL	Roman	GÓRECKI
SE	Emma	PETTERSSON
SE	Imran	ALI
SE	Krister	BLODÖRN
SI	Katja	VERDNIK

SI	Nataša	PETROVIČ
SI	Petra	ČEBAŠEK
SI	Vladka	LEŠER
SK	Dávid	DRÁB
SK	Denisa	MIKOLASKOVA
SK	Olga	ROMAN
SK	Ružena	PILIŠIOVÁ
SK	Vladimíra	POLOHOVÁ

EU COMMISION ATTENDERS

Name	SURNAME
Vincent	DELVAUX

OTHER EUROPEANS AUTHORITIES

AUTHORITY	NAME	SURNAME
EFSA	Marco	BINAGLIA
EFSA	Martina	PANZAREA
PT/EFSA	Francisca	ALMEIDA

ACCREDITATED STAKEHOLDERS ORGANISATIONS

Biocides for Europe (Cefic)	Boris	VAN BERLO
AISE	Marie	DARRIET
PSCI= Peta International Science Consortium	Tess	RENAHAN
EurEau	Eduardo	AROZAMENA
EurO3zon	Roman	GYSSELS
AISE	Joanna	KUPNY

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Kurita Europe GmbH
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TOTO
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LANXESS
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Katya	VASILEVA
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Timo	ROCKE
Kai	CRAENEN
Claudio	CARLON

WG-I-2024

Final minutes

11 June 2024

Minutes of Efficacy WG-I-2024

12, 13 and 14 March 2024

Meeting of the Efficacy Working Group of the Biocidal Products Committee

11. Efficacy Working Group

1. Welcome and apologies

The Chair welcomed all participants to the Efficacy Working Group (EFF WG) meeting and informed them that this meeting is split into three consecutive days. The list of attendees is given in Annex 1.

2. Administrative issues

SECR gave brief information on the administrative issues.

3. Agreement of the agenda

The Chair introduced the agenda items. The EFF WG agreed on the proposed agenda.

4. Declarations of potential conflicts of interest in relation to the agenda

The Chair invited all members to declare any potential conflict of interest to the agenda items. None was declared.

5. Minutes

DE, AT and NL had sent comments on the EFF WG-IV-2023 draft minutes. The revised draft minutes of WG-IV-2023 were agreed at the meeting.

6. Discussion of active substances

6.1 Medetomidine PT 21 PT 21 (eCA NO)

Please, refer to the confidential minutes in the form of the discussion table for more details.

6.2 Dinotefuran PT 18, PT (eCA BE)

Please, refer to the confidential minutes in the form of the discussion table for more details.

6.3 Polymeric betaine PT 8 (eCA EL)

Please, refer to the confidential minutes in the form of the discussion table for more details.

6.4 Early WG on 2-octyl-2H-isothiazol-3-one (OIT) PT 6, 7, 9, 10, 13 (eCA FR)

Please, refer to the confidential minutes in the form of the discussion table for more details.

7. Discussion of Union Authorisations

7.1 UA for a product family containing Hydrogen peroxide PT 4 (eCA AT)

Please, refer to the confidential minutes in the form of the discussion table for more details.

7.2 UA for a product containing Propan-2-ol PT 2 (eCA FI)

Please, refer to the confidential minutes in the form of the discussion table for more details.

7.3 UA for a product containing Propan-1-ol; Propan-2-ol PT 1 (eCA DE)

Please, refer to the confidential minutes in the form of the discussion table for more details.

7.4 UA for a product family containing Mixture of 5-chloro-2-methyl-2H- isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (Mixture of CMIT/MIT) PT 4, 11 and 12 (eCA NL)

Please, refer to the confidential minutes in the form of the discussion table for more details.

7.5 UA for a product family containing Margosa extract from cold-pressed oil of the kernels of Azadirachta Indica extracted with super-critical carbon dioxide PT 19 (eCA FR)

Please, refer to the confidential minutes in the form of the discussion table for more details.

7.6 UA for a product family containing Peracetic acid PT 2, 3 and 4 (eCA NL)

Please, refer to the confidential minutes in the form of the discussion table for more details.

7.7 UA for a product containing Glutaral (Glutaraldehyde);Mixture of 5-chloro-2-methyl-2H- isothiazol-3-one and 2-methyl-2H-isothiazol-3-one PT 6, 11 and 12 (eCA FR)

Please, refer to the confidential minutes in the form of the discussion table for more details.

8. Article 75(1)(g) requests

8.1 Formaldehyde released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1 and 3:2), PT 6, 13 (eCA AT)

AT presented the BPC opinions of Formaldehyde released from the reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1 and 3:2) in PT 6 and 13 revised based on the WG discussion that took place in the EFF WG-IV-2023. The EFF WG agreed on the opinions without discussion.

9. Technical and guidance related issues

9.1 Draft resistance guidance (FR)

A presentation was made by FR to give an overview of the actions already taken and to discuss further points:

- Discussion of the consolidated document (revised literature review part and new part on the assessment of collected data);
- Inclusion of classification of resistance risk and proposal of decision tree;
- Inclusion of FUS linked to decision tree;
- Resistance monitoring.

The first discussion concerned the literature review. FR proposed to add the requirement to update literature review at product authorisation. It was discussed, that if critical information arises about the resistance, it should be assessed at the product level. Otherwise, the assessment will take place at active substance approval or renewal. Article 47 of the BPR provides the legal provisions for handling such new information. It was agreed that the SECR will clarify the consequences of applying the BPR. The following sentence was agreed to be added: *"At product authorization, it is usually acceptable to make a reference to the CAR. An update of the literature review should be provided in the case of target organisms considered*

as target vector species, in order to check if more recent relevant or critical information on the active substance is available.".

Relevant data (section 2.2.3 of the draft resistance guidance) from the outcome of the EFF WG-IV-2022 was proposed to be revised as such: *"Evidence of resistance should preferably come from investigations in the field or on organisms collected from the field. Data from laboratory evolution studies may also be used to estimate the development of resistance when it is of sufficiently high quality (see data reliability in literature review template) and mimic practical use conditions (i.e. not conducted under induced conditions); it should however ideally be accompanied by appropriate field data."* It was discussed that since there is a risk of active substance dossiers not having field data, the option of accepting high-quality laboratory tests was not excluded.

To the same section (2.2.3) it was agreed during EFF WG-IV-2022 that the literature review template is uploaded as a part of the IUCLID dossier. Additionally, FR proposes to attach the template also to the PAR for the accessibility of applicants and Member States. The SECR will cross-check the possibility of adding the template as an appendix to the PAR. It was also discussed that if the literature data has not changed after the active substance approval, then a sentence should be added that references to the CAR.

Other suitable data (section 2.2.4) wording was amended as following: "*In addition to data on the active substance and/or corresponding biocidal products that covers development of resistance, relevant properties (e.g. physico-chemical, residual effect, …) of the active substance that will further influence its potential to cause resistance should be collected.*".

The second discussion concerned assessment of the collected data. The sentence in section 3.1 was amended as such: "*It can be sufficient to first answer question #1. If there is relevant literature showing no resistance or risk thereof, the other questions can be skipped. If there is no relevant or unavailable literature, questions #2 and #3 should be answered before proceeding with the assessment*.". It was mentioned that unavailable data could also mean that the topic is not of interest at the moment and therefore not yet investigated.

The questions and answer options of the decision tree were amended by the working group members. If there is existing data in the LR then question 1: "*What is the level of evidence present in the literature of resistance and/or cross-resistance to the active substance or a structurally closely related compound?"* can be answered with the following options: "*no evidence – low risk*", "*limited evidence – medium risk*" or "*substantial evidence – high risk*". Question 2 was proposed as such: "*Does the mode of action of the active substance involve a single biochemical target site?"* and question 3: "*Is the active substance stable (see section 2.2.4, e.g. can evaporate over the period of use) under in use conditions?".* If the answer for both Q2 and Q3 is "*no*" then it is considered low risk. If at least one question is answered with "*yes*" then it is uncertain risk.

The third discussion concerned resistance management strategies. The RMM sentences were proposed to be categorised by the level of risk. If the RMM sentences are included in the document "*Frequently used sentences in the SPC and translations*" managed by the CG then any general amendments seen necessary by the EFF WG should be proposed to the CG, in order to harmonise the use of the RMMs. The next update of the document will start in February 2025. FR proposed to compose a table with the same structure as in the CG document where they will list the sentences, their respective PTs and whether they are for professional or non-professional use.

The fourth discussion concerned resistance monitoring. Examples of monitoring protocols of different projects were introduced. Due to the different situations in the Member States, complexity of the requirements and the mandate, it was agreed that the monitoring part will be excluded from the guidance for the time being.

It was concluded that the principal steps for resistance assessment are literature review (tools: LR template, MoA resistance document), classification of AS in resistance risk categories (mainly on AS level) and then choice of suitable RMMs for the respective uses (mainly at PA stage), literature review at active substance renewal, and in some cases at product authorisation.

The next step will be the finalisation of the draft resistance guidance. The EFF WG members will have the chance to comment on the draft before the next WG discussion. Furthermore, it was confirmed by the SECR that MoA resistance document can be made accessible and continuously updated by the WG members in the Collaboration tool.

9.2 TAB proposal - Evaluation of PT 18 products against tropical (unicolonial) ants (DE)

DE introduced the TAB proposal and clarified the biological differences between native and tropical ants, gaps in the current guidance and problems associated with the treatment according to the current guidance which might lead to the spread of ant colonies and resistance development.

The EFF WG agreed with the proposal that for products against tropical (unicolonial) ants only 100% population reduction/mortality is acceptable.

The question about restricting the user category of products against tropical (unicolonial) ants to trained professionals will be transferred to the CG. The opinions about this restriction diverged between members as the general public cannot distinguish different ant species. However, due to the behaviour of unicolonial ants it is important to perform the treatment in the apartment building as a whole instead of separate apartments. It was also discussed that the consumers should be informed about the differences of the native and tropical (unicolonial) ants.

Terms "tropical", "unicolonial" and "native" were discussed. Native ants can also be unicolonial. However, in the current guidance only "tropical" is used. It was agreed that in the TAB document "tropical/unicolonial" will be used.

Also, the test species for general claim against tropical ants were discussed and it was questioned whether general claim can be accepted for surface treatment products. No agreement was reached, and it was decided to launch an e-consultation and to have a WG discussion in the near future.

10. AOB

10.1 Other information

A brief update on the upcoming EFF WG-II-2024 meeting was provided including the deadlines for the early WG discussion requests and working document submissions. SECR kindly reminded that all points in the RCOM tables should be clearly indicated as open, or closed by the eCA and that the commenting MSs should provide their replies at the appropriate time.

There were two requests from the WG members:

- to add the submission date of the UA and AS dossier to the RCOM table. This would facilitate the WG members to apply the requirements of the relevant guidance when commenting.
- to place in Collaboration the relevant documents for commenting in track change mode and not anonymise automatically the comments made.

SECR will forward these requests to the responsible persons.

In addition, several updates related to:

- updated AS Working Procedure
- the public version of the Assessment Report and embedded documents
- discussion on overdosing of biocidal products

were shared with the WG members.

Annex 1

Efficacy WG attendees

Members and advisors		
AT	Bernhard	WIDHALM
AT	Dominik	ALTMANN
AT	Isabel	KRIEGL
BE	Abla	ANENE
BE	Anastasia	BURMISTROVA
BE	Cyprien	VANREPPELEN
BE	Jennifer	PIROTTE
BE	Minh-Dung	DANG THY
BE	Natania	PEELMAN
BE	René	BAY
CH	Eliane	WANDELER
CH	Frédéric	SANS-PICHE
CH	Manuel	RUSCONI
CH	Margrith	MEIER
CH	Tenzing	GYALPO
CZ	Katerina	DOLEZELOVÁ
CZ	Roman	SVEJSTIL
DE	Irina	JANSEN
DE	Juliane	FISCHER
DE	Martin	KRÜGER
DE	Ute	TRAUER-KIZILELMA
DK	Charlotte Cleyton	JORGENSEN
DK	Magnus Gammelgaard	BERTELSEN
EE	Sandra	KAOSAAR
EL	Athanasios	GIATROPOULOS
ES	Blanca	LANDA
ES	Cristina	PORTELA
ES	Lara	FAJARDO
ES	Natividad	PEREIRO
FI	Elina	RYDMAN

FI	Jenni	JOKINEN
FI	Timo	NIEMINEN
FR	Caroline	BOITIER
FR	Catherine	BILLAULT
FR	Isabelle	ATTIG
FR	Nabila	HADDACHE
FR	Yann	MAXIMILIEN
IE	Aoife	OWENS
IT	Maria Beatrice	RONCI
LV	Linda	MEZULE
NL	Bas	DEKKERS
NL	Hanneke	WIGGERS
NL	Sonja	WARMERDAM
NO	Karina	PETERSEN
NO	Marit	RANDALL
NO	Sara	KJERVIK
PL	Karolina	KASPRZAK
SE	Bengt	ASLING
SE	Diana	POSLEDOVICH
SI	Darja	DUH
SK	Juliana	JASSOVA
SK	Marta	SUPLATOVA

ECHA Staff	
Katarzyna	SZYMANKIEWICZ (CHAIR)
Mari	RAULIO
Grethe-Johanna	PLOOMPUU
Anni	HONKA
Francesco	VOLPATTI
Alik	AKOPIAN

Accredited Stakeholder Organisations (ASOs)

CEFIC	Boris	VAN BERLO
CEFIC	Pascal	SCHMAHL
AISE	Marie	DARRIET
EUROLAB	Martina	RAZZABONI
CEFIC	Ben	MAIER
CEFIC	Djamil	AZAZNA
AISE	Elaine	BLACK
EUROLAB	Frank	SCHREIBER
AISE	Hannah	CORNER
CEFIC	Lorraine	WOOLLEN
AISE	Mara	MORENO
CEFIC	Mathieu	CHATEAU

Applicants
Thor GmbH
Hagleitner Hygiene International GmbH
Solenis UK Ltd
Fraunhofer ITEM
Tevan b.v.

Minutes of Environment WG-I-2024

Including TAB entries for revision in Appendix I

15, 19-22 March 2024

Meetings of the Environmental Working Group of the Biocidal Products Committee

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 84 members, advisors or rapporteurs registered for the meeting. Three representatives from accredited stakeholder organisation registered for the meeting, with three additional experts for their relevant item. Applicants were registered for their specific substance discussions.

2. Administrative issues

SECR informed on several administrative issues.

3. Agreement of the agenda

The Chair introduced the draft agenda and the WG was invited to add any additional items. The agenda was agreed without changes.

4. Declarations of potential conflicts of interest in relation to the agenda

The Chair invited all members to declare any potential conflicts of interest in relation to the agreed agenda. None were declared.

5. Agreement of the draft minutes from WG-IV-2023

The revised minutes were agreed without any further changes.

6. Discussion on active substances

6.1 Medetomidine, PT 21 (NO)

Please refer to the confidential minutes provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3.

Action: None

6.2 Dinotefuran, PT 18 (BE)

Please refer to the confidential minutes provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3.

Action: AHF risk assessment for an unknown metabolite

6.3 5-Chloro-2-methyl-2H-isothiazol-3-one (CIT), PT 6 (FR)

Please refer to the confidential minutes provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3.

Action: None

6.4 Polymeric betaine, PT 8 (EL)

Please refer to the confidential minutes provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3.

Action: AHF related to risk assessment to UC1 and UC2

6.5 Early WG: glutaraldehyde, PT 2, 3, 4, 6, 11 and 12 (FI)

Please refer to the confidential minutes provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3.

Action: None

6.6 Early WG: Eucalyptus citriodora oil, PT 19 (CZ)

Please refer to the confidential minutes provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3.

Action: None

7. Discussion of Union Authorisation cases

7.1 UA for a product family containing Hydrogen peroxide, PT 4 (AT)

Please refer to the confidential minutes provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3.

Action: None

7.2 UA for a product containing Propan-2-ol, PT 2 (FI)

Please refer to the confidential minutes provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3.

Action: None

7.3 UA for a product family containing Propan-1-ol;Propan-2-ol, PT 1 (DE)

Please refer to the confidential minutes provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3.

Action: None

7.4 UA for a product family containing Mixture of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT), PT 4, 11 and 12 (NL)

Please refer to the confidential minutes provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3.

Action: None

7.5 UA for a product family containing Margosa extract from cold-pressed oil of the kernels of Azadirachta Indica extracted with super-critical carbon dioxide, PT 19 (FR)

Please refer to the confidential minutes provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3.

Action: None

7.6 UA for a product family containing Peracetic acid, PT 2, 3 and 4 (NL)

Please refer to the confidential minutes provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3.

Action:

- A general discussion and a TAB entry on exposure assessment considering adjacent rooms/annexes is needed (Volunteer for drafting still needed).

- Additionally, there is a need to develop a TAB entry for performing assessment for rapidly degrading substances. (Volunteer for drafting already found).

7.7 UA for a product containing Glutaral (Glutaraldehyde);Mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6), PT 6, 11 and 12 (FR)

Please refer to the confidential minutes provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3.

Action: None

7.8 Early WG: Emission scenarios for small-scale indoor disinfection, PT 3 (BE)

Please refer to the confidential minutes provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3.

Action: None

7.9 Early WG: Emission scenarios for animal transport vehicles disinfection, PT 3 (BE)

Please refer to the confidential minutes provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3.

Action: A TAB entry needs to be drafted for a specific scenario for disinfection of transporters with reduced vehicle surfaces.

7.10 Early WG: Surface decontamination in isolators with vaporised active substances, PT 2 (DE)

DE summarised the outcome of the e-consultation. No discussion was deemed necessary considering the agreement by all commenting member states that a quantitative exposure assessment for surface decontamination in isolators is not needed for vaporised active substances.

Action: None

7.11 Early WG: Preservation of aqueous fertilisers, PT 6 (DK)

Please refer to the confidential minutes provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3.

Action: None

8. Article 75(1)(g) requests

8.1 Zineb

Please refer to the confidential minutes provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3.

Action: None

9. Technical and guidance related items

9.1 Revised (draft) Emission Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional uses (PT 18) (DE)

The discussion covered two technical points as well as general issues, related to exposure but not PT18 specific, which were brought to the attention of the WG mostly but not exclusively by NL. Overall, the general issues (on misuse, RMMs, realistic-worst case, etc.) were recognized as important and worth following up, though it was acknowledged that some fall outside of the remit of the ENV WG. NL agreed to prepare a more concrete and structured proposal, introducing the general issues and providing basis for future discussion(s), including the proposed ways forward if possible. The timeline was set to beyond June 2024 since, until then, the capacities of MSs will be required for the finalization of the ESD PT18 revision.

The revised ESD PT18 document will be available mid-April 2024, the MSs will have the possibility to comment thereon by the end of May 2024. Issues, which could not be resolved bilaterally, could be further discussed at a dedicated EG meeting or WG-II-2024 (will be decided later depending on the nature and number of open points).

9.2 PT 12 assessment in paper industries

FR presented a proposal for a TAB entry related to exposure assessment in paper industries for indirect releases. Discussion took place whether direct releases to surface water should also be assessed, and it was agreed that the TAB entry will only address indirect releases and in (foreseeably rare) cases where applicants indicate that direct releases would be relevant, the assessment can be performed using the already existing PT12 ESD.

It was agreed that a quantitative risk assessment for soil and groundwater via the STP sludge application to soil should be systematically performed, unless it can be argued that based on the substance properties the assessment can be waived. Such decisions should be made on a case-by-case basis.

Specific RMM and use instruction related issues were discussed, and it was suggested to not include those in the TAB entry itself, but explore the possibility to either propose them to the list of Frequently used sentences in the SPC or the Catalogue of standard phrases for active substance approval.

It was furthermore clarified that the type of white-water circulation treated (short or long) should be specified in the SPC, if the risk assessment covers a specific type of circulation only.

9.3 How to model emissions to groundwater from wood preservatives?

DE introduced two possible approaches (stemming from TAB ENV 186) for higher tier groundwater assessment of PT8 (UC3 wood preservatives) in PEARL FOCUS modelling, which were identified during a mutual recognition procedure and suggested for further discussion at WG level. It was agreed that this technical discussion will be handled via an e-consultation, where DE and NL will bilaterally clarify how the inputs of NL can be accounted for and, if relevant, amend the e-consultation document accordingly.

9.4 Degradation in manure

Several members were unable to properly use the Excel calculation file, most likely due to having different versions of Excel. As a result, the discussion was postponed. However, based on the information available and the earlier discussions, the WG agreed that the calculations from addendum 2 seem to cover the addendum 1 calculations (though the results are not identical), but for the moment for PT 18 only. Addendum 1 is still needed for PT 3. Further comparisons to actual data from dossiers are needed.

9.5 Chesar Platform update

ECHA informed that the release of the tool has been delayed and therefore also the earlier announced external testing has been postponed. ECHA nevertheless continues with the implementation for biocides in the same pace. The comments provided by the WG on the first batch of the repository documents in an e-consultation that took place in December-January will be discussed by an Expert Group on repository documents, likely in April 2024. DE volunteered to be a member of the EG. WG Members are invited to express their interest by email after the meeting. ECHA also explained that the TAB entry 182 requires revision in line with other guidance recently published by ECHA which is different from the proposal presented at WGII2023.

10.AOB

10.1 Other information & lessons learned (SECR)

10 year anniversary of the ENV WG

It has been 10 years since the first ENV WG was held at ECHA (30 January 2014). Many of the members that are still actively participating this WG were already involved since the beginning!

Revision of WG recommendations on in-situ generated substances, their precursors and products

SECR provided an update on the ongoing revisions of WG recommendations on *in situ* generated substances, their precursors and products. The proposed revisions to the current document CA-July19-Doc.4.1 will be discussed at the 103rd CA meeting prior to its potential CA agreement in June 2024. A discussion on outstanding issues might take place at the BPC WGs II 2024, with approval aimed at WGs III 2024. The final updated recommendation is expected to be endorsed by the BPC in November 2024.

E-consultations

Please report to the WG after you had an e-consultation, unless the item is related to an already scheduled early WG discussion.

ED items in ENV WG discussion table

The chair proposed the following regarding ED conclusions for those cases where there are no ED related open points in the RCOM:

- When the eCA proposes that the AS is not an ED, the ED conclusion is not in the discussion table
- When the eCA proposes that the AS is an ED, the ED conclusion is in the discussion table

This approach has also been adopted by the Human Health WG since HH WG II 2020. The ENV WG agreed to this approach.

Identification of MSs in Minutes

The WG was asked whether in the future commenting MSs should be anonymised in the ENV WG minutes. This is current practice also in the other WG. In principle the WG members did not object against specifically mentioning the MS that made the comment, though would accept anonymising the minutes in the context of WG practice harmonisation. DE requested whether all WGs could have access to all agreed minutes from the other WGs as well.

Lessons learnt from AS accordance check (PF52)

SECR informed the WG on the lessons learnt from the recent PFs, reminding the members of the requirement to the BPR guidance applicability. SECR also reminded the WG that the eCA needs to conclude on all critical points, even in case of an unacceptable risk and/or if it would not change the final conclusion.

SECR reminded the WG of the recent CA agreement on the extension of the review program beyond 2024 (CA-Dec23-Doc.5.4 - Extension of RP beyond 2024). In case of doubt or deviations from the agreed procedure, please contact SECR.

AS working procedure

SECR noted the revised version 9.1 of the AS working procedure, applicable from 5 March 2024. It is important that the public AR must be a single pdf document without any embedded files. All relevant information from the embedded files needs to be included in the AR.

Harmonized LoEP for pyrethroid metabolites

ECHA informed that the harmonised list of endpoints for the common metabolites of pyrethroid active substances (agreed at BPC-35) is under revision. DE CA is implementing the necessary changes for the biodegradation endpoints in line with TAB ENV 182. Review schedule to be confirmed.

ECHA Guidance on the risk assessment of bees

ECHA informed that the guidance has been published according to the schedule (https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation) and that ECHA has started the discussion for the development of a biocide calculator tool for the bee risk assessment. In addition, recording of the introductory webinar is available on the ECHA Website (https://echa.europa.eu/-/getting-familiar-with-echa-s-biocide-guidance-for-the-risk-assessment-of-bees). It was also reminded that agreement on the warning sentence for biocidal products containing hazardous substances to bees is recorded in the CA document from Dec 2023 (https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/5e6cf719-8286-4cbf-9b1e-f01eade08bb7/details).

Next WG meetings

It is not yet decided whether the next WG is a virtual meeting or a physical meeting, but the next meeting will take place between 10-21 June 2024. Addition of agenda items for the next WG can be requested by 29 April 2024 (including early WG discussions). E-consultations intended to be discussed at ENV WG II 2024 should be (ideally) launched by 10 April if intended to be discussed at ENV WG II 2024, to provide enough time for commenting and preparation of the WG discussion.

Need for dedicated AHEE meeting 2024

An AHEE dedicated meeting was scheduled for ENV WG I 2024. The chair would appreciate feedback whether this is a sufficient solution to better address AHEE related items, or whether a dedicated AHEE meeting is still desired. In case of a dedicated AHEE meeting, please list topics to be discussed.

Third AS info session for CAs

On 26 March 2024, SECR will organise the third AS info session for CAs. Invitations were sent to all BPC members/alternates, WG members and CA contact points on 9 February 2024. The info session consists of two dedicated sessions:

- Session 1: IUCLID integration
- Session 2: ED data requests for Review Programme substances

After the info session, there will be an option to schedule 1:1 session with SECR to discuss ED data request needs.

Appendices:

- Appendix I: List of TAB entries for confirmation by WG members
- Appendix II: Environment WG attendees

Appendix I: List of TAB entries for confirmation by WG members

- ENV 182 - Temperature correction and molar activation energy (Ea) for biodegradation processes and hydrolysis in water
- ENV XXX - Revision of PT12 scenarios for slimicides in paper production processes with indirect releases via STP with a biological treatment

13. ENV 182 - Temperature correction and molar activation energy (Ea) for biodegradation processes and hydrolysis in water

Below is the updated TAB ENV 182 that was first presented in the minutes of WG-II-2023, however required a further update stemming from revisions proposed under REACH and CLP. The changes (from the version presented at WG-II-2023) are highlighted in yellow and consist in the use of the same generic activation energy (65 400 KJ/mol) for both biodegradation and hydrolysis.

ENV182

Temperature correction and molar activation energy (*Ea*) for biodegradation processes and hydrolysis in water

Version 2 (AHEE-3, WG-III-2020, WG-II-2023, WG-I-2024)

The current BPR guidance (Vol IV, Parts B&C, 2017) provides an equation for temperature correction (Equation 28):

$DT50\ (X°C) = DT50\ (T)n * e^{(0.08(T-X))}$

with T being the experimental temperature and X the compartment temperature (e.g., 12°C).

It is to be noted that the Equation 28 (Vol IV, parts B&C) is a variation of the Q10 approach. Since Q10 is derived for a temperature difference of 10°C and temperatures of 10°C and 20°C, equation 28 is applicable to the same restrictions.

Equation 28 has been used outside of its original applicability domain in allowing temperature corrections other than from 20°C to 10°C. A wider applicability is however incorrect since equation 28 effectively entails multiplication by Q10. Moreover, the equation is inaccurate due to rounding of the value contained in the exponent.

It was agreed to use the Arrhenius equation in the form below to correct biodegradation or hydrolysis rates in the temperature range of 0 to 30°C:

$$\boldsymbol{DT50(T_1) = DT50(T_2) \cdot e^{((Ea/R) \cdot (1/T_1 - 1/T_2))}}$$

or

$$\boldsymbol{k(T_1) = k(T_2) \cdot e^{((Ea/R) \cdot (1/T_2 - 1/T_1))}}$$

Note that temperatures in the equations should be entered in degrees Kelvin.

Explanation of symbols

(Bio)degradation

DT50(T1)	half-life for (bio)degradation at standard compartment temperature		[d]
DT50(T2)	half-life for (bio)degradation at experimental temperature		[d]
k (T1)	degradation rate constant for (bio)degradation at standard compartment temperature		[d^{-1}]
k (T2)	degradation rate constant for (bio)degradation at experimental temperature		[d^{-1}]
T1	standard compartment temperature; T1 = 285.15 K (12°C) for freshwater and terrestrial environments, 282.15 K (9°C) for marine environments, 288.15K (15°C) for an STP		[K]
T2	experimental temperature		[K]
Ea	activation energy for (bio)degradation*		65 400 $J.mol^{-1}$
R	gas constant	8.314	$mol^{-1}.K^{-1}$

* A default value of 65 400 $J.mol^{-1}$ for *Ea* is applicable for both biodegradation and hydrolysis. Whenever an experimental, substance-specific, *Ea* value is available (for instance derived from a hydrolysis study according to OECD 111 guideline), it can be used instead of the generic value.

The background document including further information is provided in the CIRCABC TAB repository (entry "ENV182…"):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

Type of entry:	b) Clarifications/existing guidance
Publication date:	xx/xx/2023

Date of applicability for active substances:	xx/xx/2023
Date of applicability for products:	xx/xx/2023

14. ENV XXX - Revision of PT12 scenarios for slimicides in paper production processes with indirect releases *via* STP with a biological treatment

For the TAB entry

ENV XXX Revision of PT12 scenarios for slimicides in paper production processes with indirect releases *via* STP with a biological treatment

Version I (WG-I-2024)

Revised scenarios and clarifications for PT12 in paper production processes are provided in the CIRCABC TAB repository (entry "ENVXXX…"):

https://webgate.ec.europa.eu/s-circabc/XXXXX

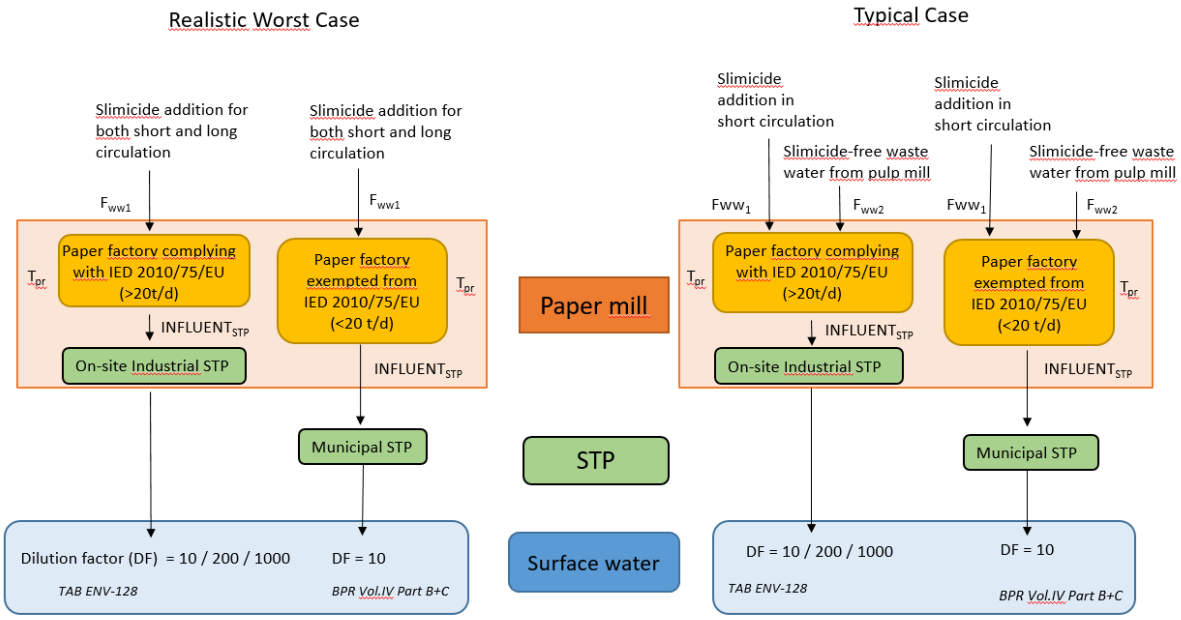
These scenarios cover only paper factories with indirect releases *via* STP with a biological treatment step.

For the repository

ENV XXX Revision of PT12 scenarios for slimicides in paper production processes with indirect releases *via* STP with a biological treatment

The following proposal for revised PT 12 scenarios (slimicides in paper production processes) only concerns indirect discharges *via* STP with biological treatment step. In case of direct discharges (claimed by the applicant in the intended uses), the worst-case approach (*i.e.* with primary settling and chemical/mechanical treatment) described in the ESD PT12 for slimicides (09.2003) should be applied.

New proposed approach (ESD PT12 revision):



For the use of slimicides in paper production processes, the ESD for PT12 (EUBEES, 2003) provides two emission scenarios:

- In the realistic worst-case scenario, the paper factory receives concentrated pulp from pulp mill (without dilution).
- In the typical case scenario, the paper plant is connected to slimicide-free water from a pulp mill and only the short circulation is treated (additional dilution).

On this basis, two situations can be distinguished: the large paper factories producing more than 20 tons of paper per day and the small ones producing less than 20 tons of paper per day.

Case of paper factories that complies with the Industrial Emissions Directive 2010/75/EU (paper production > 20 tons/d):

Please note this scenario only concerns paper factories with indirect discharges *via* STP with a biological treatment step, and for which the following sentence which must appear systematically in the SPC: *"Application is only allowed in paper factories that comply with the Industrial Emissions Directive 2010/75/EU where wastewater is purified in an on-site industrial sewage treatment plant including a biological treatment step in accordance to the Best Available Techniques (BAT) as prescribed in the BAT-reference document (BREF) for the production of pulp, paper and board".*

These factories must comply with the Best Available Techniques (BAT) for the production of pulp, paper, and board[1]. Wastewater is discharged to surface water *via* a sewage treatment plant including a biological treatment step (*i.e.* in accordance with SimpleTreat 4.0). Effluents

[1] Commission Implementing Decision of 26 September 2014 establishing the best available techniques (BAT) conclusions, under Directive 2010/75/EU of the European Parliament and of the Council, for the production of pulp, paper and board (2014/687/EU)

from these paper mills can be discharged to an on-site industrial STP (majority of the installations) or to an off-site industrial STP (minority cases).

In the case of on-site industrial STP, predicted environmental concentrations in surface water can be calculated considering a default dilution factor (DF) of 10 recommended in the BPR Guidance and assuming a complete mixing of the effluent in surface water. Moreover in this specific case, the biocide user is both the owner of the paper factory and of the waste water treatment plant and is therefore aware of the waste water volumes and the properties of the receiving freshwater body. Higher dilution factors as specified in TAB2.1 ENV-128 (WG-II-2014) are considered applicable in this case. According to the TAB2.1 ENV-128 (WG-II-2014)[2], the dilution factors for freshwater recipient can be extended to 200 and 1000. A reverse calculation to find out the precise dilution factor needed to reach acceptable risks, rounded up to nearest 10 (for dilution factors<100) or 50 (for dilution factors >100), can also be calculated. For both approaches, the dilution factor cannot be higher than 1000 according to the BPR Guidance Vol IV Part B+C.

In the second minority case (off-site industrial STP), predicted environmental concentrations in surface water are calculated considering a default dilution factor of 10 recommended in the BPR Guidance Vol IV Part B+C and assuming a complete mixing of the effluent in surface water. Higher dilution factors are not considered applicable in this case. As it is a minority case, this second case is not further discussed in this TAB entry and at the time being it can be regarded as sufficiently covered by the case of on-site industrial STP. If further experiences in the product authorization process show a need to include an assessment of this minority case, this TAB entry still provides an assessment approach for off-site industrial STP in a footnote below the second table "Input parameters for calculating PEC surface water".

Case of paper factories exempted from the Industrial Emissions Directive (paper production < 20 tons/d)

Please note this scenario only concerns paper factories with indirect discharges *via* STP with a biological treatment step, and for which the following sentence must appear in the SPC: "*Paper factories that are exempted from the Industrial Emissions Directive must discharge to the municipal sewer."*

Paper factories producing less than 20 tons of paper daily are exempted from the Industrial Emissions Directive. These factories are allowed to discharge to the municipal sewer instead of on-site waste water treatment in accordance to the best available techniques. Applying the default waste water production (15 m³/ton of paper), these factories produce 300 m³ waste water daily. Predicted environmental concentrations in surface water must be calculated considering a default dilution factor of 10 recommended in the BPR Guidance Vol IV Part B+C and assuming a complete mixing of the effluent in surface water. Therefore, higher dilution factors after municipal STPs are not foreseen according to the BPR Guidance.

[2] See "Note: Environmental assessment of biocides in PT 11 cooling water systems"; ESD specific ECHA webpage, PT 11: http://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation/emission-scenario-documents

Input parameters for calculating the local emission for the typical and worst-case scenarios of the two types of installations (that comply or not with the Industrial Emissions Directive 2010/75/EU) are summarized in the table below:

Input parameters for calculating the local emission					
Input	**Parameter**	**Value**			**Equation/ Remark**
		Typical-case scenario	**Worst-case scenario**		
Concentration of a.s in process water according to user's instructions	Cprod				S
Treatment of both long and short circulation with slimicide[1]	-	no	yes		D
Fraction of the total waste water flow coming from the short circulation of the wire part	Fww1	0.6	1		D
Connection to pulp mill	-	yes	no		D
Fraction dilution of slimicide-free waste water with waste water from pulping	Fww2	0.5	0		D
Total fraction of the slimicide lost in the dry end of the papermaking machine	$F_{total\ loss,\ paper}$	0.1			D
Theoretical concentration of a.s. (e.g. assuming no	Cp				O - Cpaper = Cprod x Fww1 x

degradation) in paper mill before waste water treatment	a_{per}				(1-Fww2) x (1-$F_{total\ loss,\ paper}$)
Rate constant of a.s. removal during the paper production process (at 20 °C)	k_{deg1}				S - TAB entry ENV 238
Hydraulic retention time for paper making process	T_{pr}	0.167			D
Theoretical concentration of a.s. in influent to STP	$Clocal_{infl-STP}$				O - $Clocal_{infl-STP}$ = $Cpaper*e^{(-kdeg1*Tpr)}$
Influent from the paper mill to the industrial STP or municipal STP 1) Paper factories that comply with IED directive (>20 tons of paper/d) 2) Paper factories that are exempted from IED directive (<20 tons of paper/d)	$INFLUENT_{STP}$	1) 5000 2) 300			D
Local emission rate from paper mill to industrial STP or municipal STP	$Elocal_{STP}$				O – $Elocal_{STP}$= $Clocal_{infl-STP}$*$INFLUENT_{STP}$* 10^{-3}

After the treatment by the industrial on-site STP or municipal STP (classical calculations not presented here), different dilution factors (DF) can be applied to calculate PEC in surface water in function of the plant:

Input parameters for calculating PEC surface water					
Input	**Parameter**	**Value**			**Remark**
		Typical-case scenario	**Worst-case scenario**		
Dilution factors in surface water after industrial on-site** STP or municipal STP 1) Paper factories that comply with IED directive (>20 tons of paper/d) 2) Paper factories that are exempted from IED regulation (<20 tons of paper/d)	DF	1) 10; 200; 1000* or carry out a reverse calculation to find out a precise dilution factor: rounded up to nearest 10 (for dilution factors < 100) or 50 (for dilution factors > 100) 2) 10			1) TAB entry ENV 128 or set by reverse calculation 2) Vol. IV Part B+C

* Maximal acceptable dilution

** For industrial off-site STP, the maximal dilution factor is set to 10

Risk assessment for soils:

A quantitative assessment for indirect emission to soils (and groundwater) via STP sludge spreading on land shall be conducted except for very specific substances based on e-fate properties.

Risk mitigation measures:

- For soils:

  When unacceptable risks for soils (or groundwater) are foreseen for indirect emissions *via* a municipal STP or an industrial off-site STP, no risk mitigation measure is applicable.

  In case of industrial on-site STP, the following RMM can be used: "Do not apply industrial sludge to soil"

- For surface water:

In case of unacceptable risks for surface water for paper factories that comply with IED (>20 tons of paper/d), with on-site industrial STP, higher dilution factors (DF) than the default factor of 10 can be proposed (default DF from TAB entry ENV 128 or set by reverse calculation). The following RMM can be used: "The effluent must be diluted at least X times."

If dilution factors to reach acceptable risks for surface water are different for the worst case and typical case scenarios, a single RMM independent on how the factory is designed should be used, considering the worst-case dilution factor.

- White water definition and restrictions:

  According to BPC-49 and 82nd SCBP meeting, "white water" should be considered as all the recirculated process water of a paper machine.

  Therefore if risks are foreseen for the worst case scenario and acceptable for the typical case scenario, the use should be restricted in the SPC to the treatment of the white waters from the short circulation circuit only. In that case, the following RMM can be used: "The product can be used only for the treatment of white waters (short circulation) in plants connected to a slimicide-free water from a pulp mill".

- Case of small paper factories not connected to pulp mill

  For the typical case scenario, risks can be refined considering only the long circulation dilution (Fww1=0.6).

  In that case, the following RMM is accepted: "The product can be used only for the treatment of white waters (short circulation) ~~in plants connected to a slimicide-free water from a pulp mill~~".

Appendix II: Environment WG attendees

Member state		
AT	Christian	Kantner
AT	Iris	Buchner
AT	Isabel	Kriegl
AT	Lea	Breul
BE	Anne	Brasseur
BE	Bart	Heulens
BE	Cassandra	Lievin
BE	Céline	Leroy
BE	Frédéric	Lefèbvre
BE	Samuel	Huerga-Fernández
BE	Sofie	Tijskens
BE	Wiet	Raets
CH	Maria	A MARCA
CH	Petra	Kunz
CH	Tenzing	Gyalpo
CZ	Pavla	Lakdawala
DE	Anja	Kehrer-Berger
DE	Daniel	Frein
DE	Eleonora	Petershon
DE	Jan	Achtenhagen
DE	Julia Margaretha	Anke
DE	Katja	Michaelis
DE	Sascha	Setzer
DE	Torsten	Schwanemann
DK	Daniel	Emil Ottosen
DK	Henrik	Wennermark
DK	Jesper	Johannessen
DK	Mette	Bøhnke
DK	Nina	Falk Gregersen
EE	Kadri	Kullamägi
EL	Aikaterini	Boutsini
EL	Akrivi Chara (Joy	Mouzaki Paxinou

EL	Evaggelia	Kourkouni
EL	Ioannis	Kandris
EL	Konstantina Maria	Latsou
EL	Theodosia	Fountouli
ES	Amparo	Haro-Castuera
ES	Carlos	Fernández Ramos
ES	Carolina	García
ES	Elena	Ruiz
ES	Myriàm	Martín Vallejo
FI	Jaana	Pasanen
FI	Jenni	Jokinen
FI	Oskari	Hanninen
FI	Sanna	Kaukoniemi
FI	Sari	Penttinen
FR	Annabelle	GOUR
FR	Anne	Straczek
FR	Arthur	GILSON
FR	Caroline	BOITIER
FR	Caroline	Picault
FR	FANNY	HERARD
FR	Hugo	Chaigneau
FR	Jérôme	Lozach
FR	Léna	NDIAYE
FR	Séléné	VERSTRAET
FR	Stéphanie	Alexandre
IE	Alan	Breen
IE	Helena	Joyce
LU	Mathis	Wolter
NL	Barry	MUIJS
NL	Els	Smit
NL	Merel	van der Ploeg
NL	Peter	OKKERMAN
NL	Peter	van Vlaardingen
NL	ZhiChao	DANG
NO	Hilde	Andersen

NO	Karina	Petersen
NO	Marit	Randall
NO	Sanne Helene	Kristensen
NO	Terje	Haraldsen
PL	Agnieszka	Podlaska
SE	Diana	Posledovich
SE	Edda	Hahlbeck
SE	Isak	Holmerin
SE	Maja	Larsson
SE	Maria	Oursouzidou
SE	Rina	Andersson
SE	Vittoria	Viara
SE	Winnie	Nassazzi
SI	Petra	Jeločnik Pelicon
SK	Denisa	Romančíková
SK	Kristína	Fulleová
SK	Simona	LISKOVA

Accredited Stakeholder Organisations (ASOs)		
CEFIC	Yuhua	Wu
PSCI	Tess	Renahan
Euro3zon	Roman	Gyssels
CEFIC	Antoine	TRIGAUX
CEFIC	Wendy	Hillwalker
CEFIC	Ellen	Thom

Applicants
Texas
Schülke & Mayr GmbH
CID LINES
f_OXYDE GmbH
Hagleitner Hygiene International GmbH

Tevan v.b.
LKC Chem-Regs Ltd
ECOLAB
CSI
Solenis UK Ltd
Equitox
Agrobiothers Laboratoire
WCA Consulting
I-Tech AB
Thor GmbH
Rütgers Organics GmbH
LANXESS Deutschland GmbH
BASF SE
AGRIA SA
Kerona Scientific Ltd on behalf of Agria
Citrefine International Ltd.
ERM